62-114 <

6.3.1 Under the No Action alternative, describe how RML has effectively corrected and addressed each of the Priority fire safety issues identified in the 2002 fire inspection.

The 2002 Fire Protection Survey Report also notes: "Formal communications procedures are critical in dealing with the response to fire and hazardous materials incidents involving chemicals and biological agents."

(Fire Protection Survey Report, July 30, 2002)

62-115

6.3.2 Under the Proposed and No Action alternatives, describe how RML has effectively incorporated local emergency responders in its formal communications systems for fire prevention, emergency planning, preparedness and response efforts.

In the minutes of RML's Safety Committee there is a discussion on an Evacuation Plan for RML: "Kaye [Bergman] mentioned that with no general alarm yet in place for all buildings, we currently do not have a method for personnel in all parts of the grounds to hear a signal for evacuation." The minutes also noted: "Breach in air handling [of a Biosafety Cabinet] in Building 6 on April 23, 2002."

(RML Safety Committee Meeting Minutes July 18, 2002)

6.3.3 Under the Proposed and No Action alternatives, describe RML's current evacuation plan and provision for alarms systems alerting all RML employees to evacuate the facility.

62-116

Under the No Action alternative, describe how RML meets or exceeds requirements of all applicable codes, standards and guidelines of the National Fire Protection Association, National Institutes of Health and National Electrical Code.

Under the Proposed and No Action alternatives discussion (DEIS 3-4 and 3-5) of affected environment fails to disclose levels and availability of local Hazardous Materials training, equipment and response personnel for existing or needed contingencies at RML

62-117 $\left\{ \begin{array}{l} 6.3.4 \text{ Describe the procedures for verifying the efficacy and safety of protective gear and lab equipment at RML.} \end{array} \right.$

As late as December 2000, Rocky Mountain Labs had no procedure in place to ensure that pathogens received by the facility were inactive as required. Additionally, lab safety hoods were not operating properly, and deficiencies in air handling were still being identified.

(RMMB Meeting Minutes, Claude Garon, Lori Lubke, Dave Dorward, Fred Hayes, Elizabeth Fischer, and Penny Gaddy-Rhodes present, Discussion Processing Samples in RMMB, December 4, 2000)

Comment

Response

- The recommendations have been addressed through training, access for first responders, and preventive maintenance contracts have been initiated and in some instances completed. Radios, alarms, and personal protective equipment have been made available. A memorandum of understanding with the local fire department is being executed.
- 62-115
 RML staff meets periodically with representatives from the FBI, U.S. Attorney's Office and other local law enforcement to share information and strengthen communication among these groups. RML is a member of the Montana Anti-Terrorism Task Force, and the Ravalli County Local Emergency Planning Committee, and the Ravalli County Terrorism Preparedness Task Force and will participate in the Ravalli County Pre-Mitigation Plan authorized under the Disaster Mitigation Act of 2000.
- RML's evacuation plan focuses on four response procedures. They include: total evacuation, shelter in place, lockdown, and room clear. The nature of the emergency determines the response. Evacuation drills are conducted semi-annually. Alarm systems consist of an audible alarm and a strobe light. The evacuation team has 50 full time employees.
- **62-117** Depending on the system, inspections occur with each use, daily, monthly, quarterly, and annually.

- **62-118** 6.3.5 Describe the procedures for verifying that pathogens transported to RML are inactive, and how these procedures will be implemented for BSL-4 pathogens.
- 62-119 6.3.6 Describe the procedures for verifying operational capability of safety features on biosafety cabinets.
- 62-120 6.3.7 Describe in detail what, if any, consequences are instituted at RML for lab employees who fail to follow safe practices and procedures for studying and handling biological agents.

6.4. Impact on the Environment is not disclosed.

6.4.1 Air Quality.

The environmental impact of the project on air quality must be discussed in greater detail. The only data given is Table 4-4 (DEIS 4-14) showing potential maximum emissions. This is inadequate to assess the actual impacts of the proposed project and does not take into account the pollution prevention mandate of the Department of Health and Human Services. A full comparative analysis is required to show existing air quality conditions, the impact on air quality from the preferred alternative, the impact on air quality from pollution prevention alternatives (such as elimination of the incinerator as a disposal method, and the use of SCONOX technology.) Please include the following information:

No Action Alternative:

Current emissions (at current average use levels)

Current maximum potential to emit

Impact on ambient air quality (i.e. the results of analysis done by Doucet and Mainka, 1999)

62-121

Preferred Alternative:

Expected emissions (at expected use levels)

Expected maximum potential to emit

Impact on ambient air quality (including during atmospheric inversions)

Pollution Prevention Alternatives:

Expected emissions (at expected use levels)

Expected maximum potential to emit

Impact on ambient air quality (including during atmospheric inversions)

6.4.2 Lack of analysis of impact to nearby Selway Bitterroot Wilderness.

The nearest Class 1 Area is the Selway Bitterroot Wilderness just six miles west of RML. Section 4.7.1.1 of the DEIS states:

"The air modeling analysis conducted for RML predicted air emission would be within Montana and federal air quality standards. These emissions are not expected to visibly affect or modify air quality in Class I areas." (DEIS 4-14)

Comment	Kesponse
62-118	Pathogens are not required to be inactive to be transported.
62-119	Please see Section 1.7.1 were requests for additional information on the alternatives were addressed.
62-120	Administrative penalties are applied as prescribed by Personnel regulations.
62-121	Please see Section 1.7.3 where comment on the impacts on air quality were addressed.

No source is referenced for this analysis. Simply stating that the impacts on air quality are not expected to affect the Class 1 area does not constitute "evidence that the agency has made the necessary environmental analyses." (40 CFR 1502.1) The analysis should be clearly explained, referenced and included as an appendix in the DEIS.

6.4.3 Lack of analysis of air quality during inversions.

The analysis referred to (DEIS 3-16) regarding modeling of meteorological data with respect to atmospheric inversions should also be clearly explained, referenced and included in the DEIS. All analyses on the impact of air quality by the different alternatives should consider the impact on air quality during atmospheric inversions.

6.4.4 Unclear claims on particulate matter emissions.

Section 4.7.2. Cumulative Effects, states:

"Under the Proposed Action the minor increase in emissions would be added to emissions from the other 11 permitted sources in the county. A decrease in particulate matter emissions from reasonably foreseeable actions would occur as undeveloped areas are used for buildings and paved for parking." (DEIS 4-14)

As stated above, no data is included to allow one to compare current emissions with expected emissions. Thus, the phrase "minor increase in emissions" is vague and subjective. The phrase needs to be clarified with data. Secondly, the confusing claim that particulate matter emissions would decrease is also unjustified with data. No data is presented (nor any analyses referenced) regarding current or expected fugitive dust emissions, which might decrease with development and paving. The DEIS appears to imply that this uncalculated decrease in particulate matter emission are expected to offset the "minor increase" in particulate matter emissions that are predicted by the increase in use of the incinerator, the added emergency generator and new boiler. This claim is highly doubtful and must either be justified with data, or reworded for accuracy.

6.4.5 Surface Water - Failure to disclose impacts.

Failure to disclose impact on MPDES permit.

Rocky Mountain Laboratories currently holds an MPDES permit for discharge into the Bitterroot River. This permit is never mentioned in the DEIS. If there are any impacts to this permit or this discharge on surface water, it should be clearly states in the DEIS. If there are no impacts, this should also be clearly stated.

62-126 6.4.6 Ground Water quantity and quality – Failure to adequately analyze impact.

The analysis of ground water does not assess the cumulative impacts of the large use by RML and the impact of the unique waste generated by RML that may end up in the ground water.

${\bf 6.4.7\ Impacts\ of\ solids\ in\ was tewater\ not\ adequately\ addressed/analyzed.}$

Section 4.8.1.1 states:

62-124

Comment Response

- 62-122 Please see Section 1.7.3 where impacts on air quality were addressed.
- Please see Section 1.7.3 where impacts on air quality were addressed.
- **62-124** Please see Section 1.7.3 where impacts on air quality were addressed.
- Oncolor of the C&C ditch. The discharge outflow for this permit was located approximately 100 feet northwest and down gradient of the facility. Due to changes in facility operations, cooling water is no longer discharged and the permit was allowed to expire on November 30, 2002. An industrial stormwater permit is not required under RML's Standard Industrial Classification (SIC) Code (SIC Code 8071).
- **62-126** Please see Section 1.7.3 where impacts on water and wastewater were addressed.

"The load of solids in RML's current wastewater stream is small relative to the volume of liquid (Lowry 2003). New operations at the Integrated Research Facility would increase the solids load in wastewater from RML, but the increase is not quantifiable." (DEIS 4-15)

62-127<

While this section has more detailed information on the amount of water they expect to consume with the new lab, the DEIS claims that the increase in solids loads in RML's wastewater is "not quantifiable". The claim that the load of solids is "small relative to the volume of liquid" is referenced to a personal communication with the Director of Public Works. This is a general statement of common knowledge, not an analysis of solids loads in wastewater. The load of solids in the wastewater is an important issue - as the solids treatment at CHDPW is already at near capacity. The increase in solids need to be quantified, in order to determine if RML alone would cause the CHDPW to need to upgrade their solids handling system. The document (DEIS 3-18) indicates several ways in which the solids load would increase: increased use of the incinerator means more blow down water from the incinerator scrubber, and more dust suppression from removal of incinerator ash.

In addition, the document (DEIS 2-6) discusses the addition of the biowaste cookers, which will discharge into a 12,000-liter holding tank -which will be added slowly (in order to dilute the solids) to the rest of the wastewater stream. The identification the size of the holding tank needed indicated that an estimate of the amount of solids expected to be generated has been made. The calculation to predict the amount of solids in the wastewater is not impossible or "not quantifiable." Calculations can and must be done to assess the impact of solids from the preferred alternative on the solids load to CHDPW.

62-128*-*

6.4.8 Lack of accounting for discrepancy between water usage/wastewater disposal.

Section 3.8 states that the current average monthly water consumption is 1.7 million gallons which calculates to roughly 55,000 gallons per day (DEIS 3-18). This section later states that RML's current wastewater effluent rate is 15,000 gallons per day. Section 4.8 however states that wastewater discharge would increase by 15,000 gallons per day to a total of 60,000 gallons per day (DEIS 4-15). The discrepancy between the two wastewater estimates should be reconciled. In either case, the water consumed but not discharged as wastewater (which is either 10,000 gallons per day or 40,000 gallons per

day depending on which estimate is correct) should be accounted for in the DEIS.

62-129-

6.4.9 Wetlands - Impacts not fully analyzed.

Impact of fugitive dust from construction on wetlands.

Section 3.9.4.1 (DEIS 3-21) states that: "The closest wetland is approximately 430 feet west" of the site for the BSL-4 lab. This wetland will likely be impacted by fugitive dust and increased sediment loading from wastewater runoff during construction. An analysis of this impact and mitigation measures to prevent impacts must be included in the DEIS.

Comment

Response

Please refer to Section 1.7.3 where comments on wastewater were addressed. According to CHDPW's wastewater engineer, the CHDPW facility is already at its solids handling capacity and the City of Hamilton is planning to construct a temporary solids storage basin to meet current requirements in the interim until a CHDPW facility expansion plan is prepared. The CHDPW would need to upgrade solids handling capacity even if the Integrated Research Facility were not built.

Please see Section 1.7.3 where impacts on the community infrastructure were addressed.

Please see Section 1.7.3 where impacts on the community infrastructure were addressed.

Please see Section 1.7.3 where impacts on the community infrastructure were addressed.

6.4.10 Endangered Species.

RML claims (DEIS 3-23) that: "The proposed laboratory expansion would not disturb areas beyond the existing campus area; therefore, no effect on threatened or endangered species or their critical habitat would result from the Proposed Action."

62-131

Though the "nearest known bald eagle nest" (DEIS 3-23) is identified at the Teller Wildlife Refuge, the DEIS does not disclose how wintering and migrating bald eagles utilize the habitat adjacent to RML along the Bitterroot River for perching, foraging and loafing. Bald eagles are particularly sensitive to noise, and noise disturbances that cannot be observed from the bald eagles position.

62-132 <

Table 3-7 Measured Noise Around RML shows that dBA appears to peak on the southwest corner of campus and the west fence line (DEIS 3-9). Construction noise over the next two years combined with operation of the facility could become a human disturbance factor for threatened bald eagles. *Under the proposed action, provide a biological discussion of all direct, indirect and cumulative noise factors that could disturb bald eagles and their habitat adjacent to the RML facility along the Bitterroot River.*

"Sounds that are sporadic and observable may affect bald eagle nesting and perching behavior more than constant, predictable sounds produced by activities that can not be observed (MTFWP, Dennis Flath and Kurt Alt, and private consultant, Al Harmata per. Comm. 11/02/98, USFS Stangl pers. Comm.)." (Biological Assessment for the Horse Butte Bison Capture Facility - Site A2 Annual Operation from November 1 through April 30 Threatened and Endangered Wildlife, Janine Stangl, Sandy Kratville and Marion Cherry, November 30, 1998 page 14)

62-133

Disclose the USFWS March 11 2003 communication on threatened and endangered species and their habitat.

Yellow-billed Cuckoo

In Section 3.9.8.1, the paragraph on the Yellow-billed Cuckoo, states: "Yellow-billed Cuckoo are not known to occur in the Project Area". No reference is cited for this claim. Given the Yellow-billed Cuckoo is a transient species and select well-concealed nest sites, and has been determined by the USFWS to potentially occur on the site, additional research is needed to determine whether or not the Yellow-billed Cuckoo inhabits the site and may be impacted.

62-134≺

6.4.11 Wildlife.

62-135 -

The DEIS should include a discussion of wildlife, including deer, rodents, fish, and bird that enter and leave the compound. An analysis of their risk of contacting toxins, physical hazards, lab animals and infections should be disclosed.

Comment

Response

- Please see Section 1.7.3 where comments on the effects of Threatened and Endangered Species were addressed. Bald eagles are sensitive to loud, rapid-fire noises such as those used (with limited success) to get them to move away from military installations and airports.
- Please see Section 1.7.3 where comments on the noise analysis were addressed. Please also see response to comment 36-2.

- As stated in the EIS, the US Fish and Wildlife Service provided a list of endangered and threatened species. The list included all of Ravalli County.
- A reference has been included. Yellow-billed cuckoo habitat does not occur in the immediate location of the proposed construction.
- 62-135

 Laboratory animals are kept in biosafety containment and therefore wildlife are not at risk for contact with toxins, laboratory animals, and infections. It is not anticipated that wildlife will come in contact with any physical hazards due to construction or operation of the Integrated Research Facility or RML.

6.4.12 Solid waste disposal.

The only reference in the DEIS to the non-infectious solid waste stream generated by RML is in Section 2.1.2:

"Disposal of Non-Contaminated Material

Waste that has not come in contact with a biohazardous, radioactive or chemical material is considered non-contaminated and would be disposed of as general waste. This would make up the majority of waste from the facility." (DEIS 2-8)

The impact of solid waste should be given at least the same amount of analysis and attention as impact of wastewater analyzed in this DEIS. Stating that non-infectious waste would be disposed of "as general waste" is entirely vague. This DEIS must include a full analysis of both the current and expected solid waste stream from RML. This analysis should include a general breakdown of types of waste, and data on the quantity of waste generated and method of disposal. The breakdown of waste that is land filled versus incinerated must be presented. The financial and environmental impacts of pollution prevention alternatives including the elimination of incineration as a disposal method must be discussed in this analysis.

62-136

62-137

Cont. on next page

6.4.13 Radioactive Material Use and Waste Disposal

No reference is made in the DEIS to RML's past, current or projected use and disposal of radioactive material, yet this issue has significant impacts and effects on safety, health and the environment. A full comparative analysis of the use and disposal of radioactive material should be included for all alternatives in the DEIS.

Specifically, this analysis should at minimum:

Discuss and provide information on the status of RML's Nuclear Regulatory license #25-01203-01.

Provide current and projected data on the amounts and kinds of radionuclides shipped to RML, and generated by the facility's cesium irradiator.

Provide current and projected data on the amounts, treatment and media disposition of solid and liquid radioactive wastes at RML.

Using the last 5 years of radioactive material use and waste disposal at RML as a baseline, provide scientific information on the health risks of radiation exposure to RML employees, an individual residing in Hamilton, a fetus or embryo.

Provide a meaningful discussion and information on safe procedures for handling radioactive material in a lab environment, securing and storing radioactive material at RML and treating radioactive waste materials.

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Comment

Response

62-136

Please see Section 1.7.3 where comments on the impacts on the community infrastructure were addressed.

62-137 ≺

Provide scientific information on the cumulative impacts of RML incinerating and discharging radioactive waste into Hamilton city sewer. Include a discussion on the final disposition of incinerator ash.

Discuss and provide information of past radioactive disposal practices at RML that required environmental remediation and cleanup.

Comment

Response

62-137

Please see Section 1.7.1 of the SDIES where requests for more information on the alternatives were addressed. Information on RML handling of radioactive materials has been included under the description of the No Action Alternative and expected use under the Proposed Action in Chapter 2. RML's use of radioactive materials is regulated by the Nuclear Regulatory Commission to ensure that it has no effect on human health. Waste disposal methods are included in the description of the No Action alternative in Chapter 2. Past actions requiring remediation are outside the scope of the current EIS analysis.

7. Failure to Disclose Impacts on Local Governments.

The direct and indirect effects on government and public finance are briefly discussed in section 4.3.1.1 (DEIS 4-8). This section states:

"Public finance revenues would increase with increased income tax on payrolls from construction and operation of the Integrated Research Facility, as well as the incomes of spouses and older children of RML employees, increased number of vehicles being licensed, and property tax revenues based on additional new homes and increased property assessments. Property taxes would increase as the needs of the county, cities, and special districts increase with new populations. How much increased revenue or cost could be attributed to the Proposed Action cannot be predicted." (DEIS 4-8)

7.1 Revenues from income tax, vehicle licenses and property taxes can and should be estimated for this DEIS.

These are not impossible calculations - especially given that the DEIS has identified both the number of expected new residents to Missoula and the wages they will be paid. The financial analysis is a significant factor in determining the impact the project will have on the economy.

In Section 4.3.1.2 the DEIS states:

"The No Action alternative would not have direct economic impacts. An opportunity to stabilize the local economy with government jobs would be lost, slowing the realization of economic development goals." (DEIS 4-8)

62-138 <

The Ravalli County Economic Needs Assessment states that total personal income for Ravalli County is \$626 million, and that approximately 50% or \$313 million of total personal income represent earnings. (Swanson, 2002, p. 9) Please justify how the additional \$4.7 million in wages generated by the preferred alternative (a 1.5% increase in local earnings) would serve to "stabilize the local economy" or reword this claim for accuracy. (Swanson, 2002 Ravalli County Economic Needs Assessment, The Bitterroot Valley Economy, prepared for the Ravalli County Economic Development Authority by Dr. Larry D. Swanson, November 2002.)

The DEIS makes the following claim:

"Government job growth is particularly valuable to the community because of the relatively high wages that add to the economic base (Nicholson 2002)."

62-139 Our reading of the Nicholson report finds no such claim or conclusion. Please indicate the correct source for this statement.

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Comment

Response

Please see Section 1.7.3 where comments on 62-138 the social and economic impacts were addressed. The word "stabilize" has been replaced with the word "enhance" in the FEIS.

Please see Section 1.7.3 where comments on 62-139 the social and economic impacts were addressed. The source for this statement has been corrected in the FEIS.

7.2 Section 4.2.2 briefly discusses impacts to community safety, but does not analyze the direct and indirect economic effects of these impacts.

The section states:

"Procedures and protocols would also be established with local emergency response agencies to address responsibilities of each agency in the event of an emergency at RML." (DEIS 4-7)

62-140

These procedures and protocols will require local emergency response agencies to acquire both new equipment and extensive training. The costs for this equipment and training are economic effects of the preferred alternative and must be calculated and presented in the "Direct and Indirect Effects - Government and Public Finance" (Section 4.3.1.1 DEIS 4-8).

Comment

Response

62-140

Please see Section 1.7.3 where comments on the impacts on community infrastructure were addressed.

8. Failure to Fully Disclose Impact on Neighbors.

62-141

The environmental impacts to nearby neighbors of RML are of considerable concern and deserve much greater attention than they received in this DEIS. The DEIS should have a clear comparative analysis of current conditions and expected conditions both during and after construction of a BSL-4 facility.

8.1 Noise impacts.

62-142

The section on noise in Chapter 4 needs to be expanded and clarified. Table 4-2 (DEIS 4-9) is not clearly written. Does the "measured dBA" column refer to a maximum or average measured dBA (as more than one measurement was taken in each location)? This column should have a range that can be compared with the "predicted range" column. Also a third column for expected range of noise during construction is also needed. Comments were made at a CLG meeting that noise from RML is louder when experienced on the second floor of their homes - such as on an upstairs balcony. An analysis of sound levels at varying elevations must be in this section, and included in Table 4.2.

8.2 Transportation and Traffic impacts.

Section 4.2.1.1 (DEIS 4-5) states that traffic would increase around the RML campus both during and after construction. No estimate is given of the expected increase (in numbers of trips) of traffic during construction, but it does state that after construction the increase would be about 200 trips per day. There is however no context given for this number. An estimate of current traffic (in trips per day) must be included in this section in order to be able to assess what 200 additional trips per day would mean. An estimate of the number of trips during construction should also be included. The DEIS states that a shuttle system to an offsite parking lot may be implemented. This is an excellent example of a pollution prevention mitigation alternative which should be analyzed in the DEIS in comparison to an alternative in which all construction workers make individual trips to the site each day. These different options should be analyzed and included in the DEIS.

62-143

8.3 Traffic Safety.

62-144

There is no discussion of the impacts of the proposed project on traffic safety. Section 3.2.6. (DEIS 3-5) states that current accident rates in Hamilton have been "average" but does not provide any numerical data on numbers of accidents. This information should be included with an estimate of any increase in accidents due to increased traffic expected with the project. In addition an analysis should be conducted of construction traffic patterns and the expected impact on safety for children. Will large trucks or other machinery regularly drive past schools, parks or other locations where children cross often? How can this impact be mitigated to improve safety in these locations?

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Comment Response Please see Section 1.7.3 where comments 62-141 on the effects of the proposed action were addressed. Please see Section 1.7.3 where comments 62-142 on the effects of the proposed action on noise were addressed. Please see Section 1.7.3 where comments 62-143 on the effects of the proposed action on traffic were addressed. There is no reason to expect the accident 62-144 rate to increase due to the proposed

action. There is no need to mitigate to

improve safety because there are no

impacts on traffic safety from the proposed

action.

9. Failure to Fully Disclose Economic Impacts.

9.1 Lack of analysis of impact to housing values.

The only statement about the impact of the preferred action on the property values of neighbors is in Section 1.7.1.1 which states:

"...there is no indication that the Proposed Action will have a negative effect on property values." (DEIS 1-9)

62-145{

There is however, also no evidence that any analysis was done of the potential impact of a BSL-4 lab on nearby property values. There are other BSL-4's in the country and Canada, with nearby housing. A study should be done to evaluate the impacts of property values in the areas surrounding those labs in order to support the claim that property values will not be affected. Many studies have shown that other types of controversial development such as landfills, power plants, nuclear reactors, Superfund sites have had negative impacts on property values from the stigma of both real and perceived risk. (The Impact of Hazardous Material on Property Value available at http://www.mundyassoc.com/articles/impact.htm and An Interregional Hedonic Analysis of Noxious Facility Impacts on Local Wages and Property Values, David E. Clark, Marquette University, and Leslie A. Nieves, Argonne National Laboratory, Journal of Environmental Economics and Management, Volume 27, pages 235-253 1994.)

62-146 <

This analysis should include the effect on property values if a newsworthy release event occurs in other locations in addition to the effect on values due to a local event. This analysis should include a range of events that would increase the perceived risk and fear level in the public and, in turn, that fear level on property values.

Impacts to property values area a significant issue and must be carefully evaluated as a potential socioeconomic risk of the preferred alternative.

9.2 Failure to adequately assess whether the economic benefits from construction and operation would be local or not.

62-147 <

The DEIS should clearly show how the policies and procedures used during construction and operation would be allocated geographically. The DEIS should analyze both wages (and the location of workers) as well as the cash flow of overhead and profit (and where they enter the economy) in order adequately show the people of Ravalli County and the Decision Maker the economic benefits of the project.

Comment

Response

62-145

Please see Section 4.2.1.1 where comments on the effects of the Proposed Action on housing were addressed. Please also see response to comment 62-146.

62-146 Please see Section 4.2.1.1 where comments on the effects of the Proposed action on property values were addressed.

Please see Section 1.7.3 where comments on social and economic impacts were addressed. The DEIS (pg. 4-7) says that "The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli county..." This information is also included in the FEIS.

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Failure to Disclose Potential Conflicts between the Proposed Action and Objectives of Federal, state and local land use plans, policies and controls.

Section 40 CFR 1502.16 states that an EIS must disclose:

"(c) Possible conflicts between the proposed action and the objectives of Federal, regional, State, and local (and in the case of a reservation, Indian tribe) land use plans, policies and controls for the area concerned."

The DEIS addresses this requirement by stating:

"The RML and the proposed Integrated Research Facility meet community goals listed in the 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan." (DEIS S-3)

62-148↓

There are however several conflicts that were not disclosed but which need to be discussed in detail in the DEIS.

10.1 Conflicts with goals in the Ravalli County Growth Policy.

Ravalli County Growth Policy, Countywide Policy 1.6: "Promote control of noxious weeds."

62-149

DEIS (S-3) states that the site is currently vegetated by weeds. Disruption of soil during construction could promote weed growth onsite and on adjacent property. Please discuss how construction and landscaping of the project will be managed to prevent spread of weeds on the campus.

Ravalli County Growth Policy, Countywide Policy 2.3:

"Encourage the protection of water quantity and quality; including the mitigation of adverse cumulative impacts of private, commercial and public development."

62-150 <

Section 4.8 (DEIS 4-14) states that the preferred alternative is expected to require an additional 14 gallons per minute (7.3 million gallons per year). This will have a considerable effect on water quantity in Ravalli County. Please discuss how water consumption will be mitigated in accordance with the growth policy. For instance, what specific water conservation efforts will be implemented by Rocky Mountain Laboratories to help offset this effect?

Countywide Policy 3.3:

"Promote alternatives to burning to assure air quality."

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Comment

Response

The words "economic development" have been inserted between community and goals in the FEIS.

62-149 Please see response to comment 39-19.

62-150

Please see Section 1.7.3 where comments on City of Hamilton water supply were addressed. The analysis showed that the Proposed Action would not have a "considerable effect on the water quantity in Ravalli County." No mitigation is necessary.

Section 4.7.1 of the DEIS states:

"Incinerator use is estimated to increase from approximately two to three days a week to three to four days a week." (DEIS 4-13)

62-151-

As opposed to promoting alternatives to burning, the preferred alternative will increase burning by as much as 50 percent. Please justify why this is not a direct conflict with Countywide Policy 3.3. It is clear that alternatives to the incinerator are readily available i.e. a very inexpensive landfill in nearby Missoula. It is also clear from the DEIS that all waste that is generated by a BSL-4 is fully decontaminated before leaving the building Thus there is no need for incineration of this waste from a medical waste decontamination standpoint.

"Countywide Policy 3.6: Encourage the use of efficient heating systems."

62-152

Section 2.1 states (DEIS 2-1) that the proposed action includes a new addition to boiler Building 26 to house a new natural gas-fired boiler. Please discuss the options considered for this new boiler, and clarify why this new boiler is considered "efficient".

"Countywide Policy 4.1: Encourage development that will minimize or avoid additional costs to existing taxpayers.

and

Countywide Policy 4.5: Developers will be responsible for providing the infrastructure necessary within the development such as community water, sewage treatment and roads. A system of 'nexus and proportionality' will govern external infrastructure costs attributable to the developer."

62-153 <

Please explain in detail how the preferred alternative will be a development that will minimize or avoid additional costs to existing taxpayers. External infrastructure costs also include improved Hazmat and emergency services. Please calculate the costs of any additional training and equipment for Hazmat and emergency services that will be needed in accordance with the emergency plan for the preferred alternative. Please discuss what proportion of these costs will be attributable to RML.

"Countywide Policy 7.5: Encourage minimizing light pollution in new development in order to protect visibility of the night sky and enhance public safety."

The planned outdoor lighting for the preferred alternative is not addressed in the DEIS, despite specific scoping comments that were submitted regarding a concern about light pollution from the proposed project. In terms of setting a precedent, the flood lighting currently used on the new BSL-3 building at RML does not meet countywide policy 7.5. Please discuss the planned outdoor lighting for the preferred alternative and how it will

62-154

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meet countywide policy 7.5.

Comment

Response

Please see response to comment 62-20. Additional information has been included in the FEIS in Section 4.7.1.

62-152 Please see response to comment 39-19.

62-153 Please see response to comment 39-19.

62-154 Please see response to comment 39-19.

10.2 Lack of Discussion concerning coordination with local Emergency Planning Agencies LEPC, EPTF, Homeland Security Taskforce, Red Cross etc.

62-155

The DEIS should also address any conflicts with federal, state or local plans other than 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan.

At a minimum, the DEIS should also address any potential conflicts with the Weapons of Mass Destruction/Terrorism Strategic Plan for Montana, and both the Ravalli and Missoula County Disaster and Emergency Plans. In addition, the DEIS should include a discussion of any coordination RML has done with local Emergency Planning Agencies LEPC (Ravalli and Missoula Counties), Emergency Planning Task Force (Ravalli and Missoula Counties), the Montana Homeland Security Taskforce, State Emergency Response Commission (SERC), MT Disaster and Emergency Services and the Red Cross.

Comment

Response

62-155

Montana DES stated that the project does not conflict with the Weapons of Mass Destruction/Terrorism Strategic Plan for Montana, since it is a planning document that assesses the vulnerability of bioterrorism in Montana by county for the purpose of allocating resources for bioterrorism prevention. RML participates in the Ravalli County disaster and emergency planning. Conflicts with other jurisdictions were not identified in the EIS because none could be found.

11. Failure to Address Scoping Comments.

The DEIS failed to address scoping comments adequately. The failures regarding Range of Alternatives and the Scope of the project are discussed in Sections 4 and 5 above.

11.1 Failure to List Scoping Issues and Concerns determined to be Outside the Scope of the EIS.

Section 1.7 discusses the four categories public comments were assigned to, namely:

"Issues identified in the comments were assigned to the following four categories:

- Issue or concern that could develop an alternative;
- · Issue or concern that could result in a mitigation measure;
- · Issue or concern that could be addressed by effects analysis; or
- Issue or concern outside the scope of the EIS." (DEIS 1-8)

The first three categories are addressed in sections 1.7.1, 1.7.1.1 and 1.7.2. However, the final category - "Issue or concern outside the scope of the EIS" is not discussed at all. It is common practice in a DEIS to list the comments that were categorized as outside the scope with an explanation for each. Given that so many public comments appear to have been dismissed, and that this has caused dissension in the community, it is extremely important that the DEIS include a section detailing and justifying why public comments have been categorized as outside the scope.

11.2 Failure to Address Effects Analysis Comments Listed in 1.7.2

Section 1.7.2 lists the effects analysis comments purported to be addressed in the DEIS. Unlike Section 1.7.1, no references are included in this section as to where one can find further discussion of these issues. One reason for this is that many of the issues listed are not in fact addressed later in the EIS. For example:

11.2.1 "Impacts on community infrastructure such as schools, roads and emergency response agencies."

With respect to schools, the DEIS states that:

"Duane Lyons, Hamilton School Superintendent, reports that the middle school and high school have sufficient capacity to handle up to 100 new students. The elementary schools are at capacity; another facility is available if necessary." (DEIS 3-4)

62-157∤

62-156 ₹

The social and financial impacts of opening a new elementary school could be significant to the community and needs to be discussed in detail in the DEIS.

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Comment

Response

Please see Section 1.7.4 where comments that were considered outside the scope of the EIS were addressed. The comments determined to be outside the scope of the analysis were generally statements for or against the project or random tidbits of information that could not be formulated into an "issue." All comments are available in the administrative record. See the following few responses for how these issues were addressed.

Please see Section 1.7.3 where comments on the impacts on community infrastructure are addressed. The DEIS and SDEIS state that "School capacity is adequate for growth, especially since school-aged levels are

decreasing." There is no evidence that the Integrated Research Facility would cause the need for a new school.

With respect to roads the DEIS states that:

"New signals may be warranted at two locations on U.S. 93; one at Pine Street and another at Ravalli Street (seven blocks and three blocks north of RML, respectively." (DEIS 3-5)

62-158

It is unclear if these signals are warranted due to existing conditions or to impacts from the proposed lab. If it is the latter, a financial analysis of the new signals must be included in the DEIS.

With respect to emergency response agencies (DEIS 2-9) mentions that the Emergency Plan will be updated and emergency personnel will be notified of the types of biological materials being used in the lab. The financial impact of these actions needs to be discussed in detail. Specifically, the answers to these questions need to be addressed in the DEIS:

62-159 <

What equipment will emergency responders need to protect themselves in responding to an emergency?

What training will be required?

How will this be paid for and what will it cost to the taxpayers? Hospital staff needs to be mentioned in this section as well - What additional equipment, training or personnel will hospital staff need and what will that cost?

11.2.2 "Increased use and disposal of hazardous chemicals by the Integrated Research Facility."

There is one brief paragraph (DEIS 2-8) that states that hazardous chemicals will be handled according to federal regulations and then confusingly states that hazardous waste generation will continue to decline rather than increase. The historical trend may show a decline, but the preferred alternative will likely result in an increase from current levels. Despite a specific scoping request for detailed information on current and expected chemical use and waste disposal, the DEIS does not include any accounting for the types of hazardous chemicals to be used, how they will be disposed of, or how much increased use there will be with the new lab. As mentioned above, the Voluntary Cleanup Plan for RML released by Maxim Technologies in June 2003 includes an appendix titled: "Appendix F: Chemical Use and Chemical Waste Inventories." This information has been compiled by the very same consultants who wrote the DEIS. It must be included in the next DEIS. In addition, a detailed accounting of the expected increase in chemical usage

associated with the proposed BSL-4 lab must be included.

62-160

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Comment

Response

- 62-158 The signals may be warranted due to the current traffic situation.
- **62-159** Please see Section 1.7.3 where comments on community infrastructure are addressed.

Appendix. F of the Voluntary Cleanup Plan 62-160 was compiled by RML personnel from manifests of the shipment of hazardous wastes for the years 1986 - 2001. No volumes were given for those years. RML is classified as a "small quantity generator" of hazardous waste by the Montana Dept. of Environmental Quality. Volumes of hazardous chemical waste are not expected to increase if the Integrated Research Facility is built. Even though employee population is expected to increase 15% -20%, the recent emphasis on minimizing hazardous waste and ordering only those quantities actually needed is expected to offset that increase. Implementation of the NIH environmental management system should reinforce current efforts.

11.2.3 "Potential increased threat of outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism."

Section 4.2.1 briefly addresses these key concerns with the statement:

"Potential added risk to the community from the Proposed Action cannot be effectively quantified." (DEIS 4-2)

62-161

This is an inadequate response. A full risk assessment of the potential increased threat from these four issues (i.e. outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism) must be clearly laid out in the DEIS. The mitigation plans for each of these potential threats must also be clearly laid out in the

11,2.4 "An emergency plan to be implemented should a laboratory worker be exposed to an agent or in the unlikely release of an agent to the neighborhood."

The emergency plan is a key mitigation tool to offset the significant impacts of the preferred alternative. Simply stating that an emergency plan will be prepared before use of the facility is not in the spirit of NEPA. Detailed information about the emergency plan is equally important in assessing the potential impact of the facility as the specifications 62-162 out in Chapter 2. It is unacceptable to have one but not the other. The DEIS must include the full emergency plan.

11.2.5 "Impacts on animals used for experiments."

The only references to animals in the DEIS are found in the appendices. An analysis of impacts to animals used for experiments is never discussed. This analysis must be included in the DEIS.

Additionally, the care, treatment and facilities used to contain animals at RML needs to be included in the DEIS. Include a discussion of the humane treatment of lab animals.

The risk of an animal infected escaping into the facility and the environment must be part of the DEIS discussion.

11.2.6 "Impacts on air quality associated with the increased use of the incinerator."

The air quality section (DEIS 4-13) does not discuss the before and after levels of emissions. It has one table listing "maximum permitted potential to emit" which represent the very high levels of emissions allowable in the permit. There is no accounting for the actual levels currently experienced now (no action alternative) versus the levels that would be experienced if the lab goes in (preferred alternative). There needs to be an comparative analysis of the actual increase in air quality emissions associated with the expected increased use of the incinerator.

Comment

Response

Please see Section 1.7.3 where comments 62-161 on the increased threat were addressed.

Please see Section 1.7.2 where comments 62-162 on the emergency plan were addressed.

Please see Section 1.7.1 where questions 62-163 about animals used for experiments were addressed.

Please see Section 1.7.3 where comments 62-164 on the effects of the increased use of the incinerator were addressed.

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11.2.7 "Discontinuing the incineration of plastics."

62-165

A word search of the DEIS finds that this phrase in Section 1.7.2 is the only place where the word "plastics" is used in the entire document. *Incinerating plastics - which is of considerable concern to the community - is never discussed in the DEIS and needs to be from a public health, workplace safety and environmental perspective.*

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12. Failure to disclose adequate information about current available infrastructure.

Specific scoping comments were submitted asking the NIH to address the capabilities of the medical and emergency services in the area in detail. However, Section 3.2.5 (DEIS 3-4) only briefly discusses current infrastructure relating to community safety. This section needs to be expanded significantly. A subsection on Hazmat capability needs to be added to this section. The health care section needs to be expanded to better describe the current capabilities (and lack thereof) of Marcus Daly hospital to handle infectious disease patients. This should include the number of physicians on staff currently board certified in infectious disease, the specialized equipment (isolation rooms etc.) available etc. In addition, a section on the same capabilities of St. Patrick hospital in Missoula must also be included in this section. Simply stating that "a full range of specialty medical services are available in Missoula" is inadequate to address this important issue.

Comment

Response

62-165

In response to this comment, the effects of the incineration of plastics is addressed on page 3-16 of the SDEIS. The by-product concentration is $1/100^{th}$ of the permitted limit and well below federal standards to protect human health.

Comment

Response

62-166

Please see Section 1.7.1 where requests for additional information on the alternatives were addressed.

62-166

13. The NIH failed to prepare a Programmatic Environmental Impact Statement (PEIS) on increasing funding and thereby greatly expanding BSL-4 facilities.

The NEPA/CEQ regulations require that broad federal actions, such as proposing to double or triple the number of existing BSL-4 facilities in the U.S. be evaluated.

1502.3 - STATUTORY REQUIREMENTS FOR STATEMENTS.

"As required by sec. 102(2)(C) of NEPA environmental impact statements (1508.11) are to be included in every recommendation or report. On proposals (1508.23) For legislation and (1508.17). Other major Federal actions (1508.18). Significantly (1508.27). Affecting (1508.3, 1508.8). The quality of the human environment (1508.14)"

1502.4 - MAJOR FEDERAL ACTIONS REQUIRING THE PREPARATION OF ENVIRONMENTAL IMPACT STATEMENTS.

"(a) Agencies shall make sure the proposal which is the subject of an environmental impact statement is properly defined. Agencies shall use the criteria for scope (1508.25) to determine which proposal(s) shall be the subject of a particular statement. Proposals or parts of proposals which are related to each other closely enough to be, in effect, a single course of action shall be evaluated in a single impact statement. (b) Environmental impact statements may be prepared and are sometimes required, for broad Federal actions such as the adoption of new agency programs or regulations (1508.18). Agencies shall prepare statements on broad actions so that they are relevant to policy and are timed to coincide with meaningful points in agency planning and decisionmaking. (c) When preparing statements on broad actions (including proposals by more than one agency), agencies may find it useful to evaluate the proposal(s) in one of the following ways: (2) Generically, including actions which have relevant similarities, such as common timing, impacts, alternatives, methods of implementation, media, or subject matter. (3) By stage of technological development including federal or federally assisted research, development or demonstration programs for new technologies which, if applied, could significantly affect the quality of the human environment. Statements shall be prepared on such programs and shall be available before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives. (d) Agencies shall as appropriate employ scoping (1501.7), tiering (1502.20), and other methods listed in 1500.4 and 1500.5 to relate broad and narrow actions and to avoid duplication and delay."

1502.5 TIMING.

"An agency shall commence preparation of an environmental impact statement as close as possible to the time the agency is developing or is presented with a proposal (1508.23) so that preparation can be completed in time for the final statement to be included in any recommendation or report on the proposal. The statement shall be prepared early enough so that it can serve practically as an important contribution to the decisionmaking process and will not be used to rationalize or justify decisions already made (1500.2(c), 1501.2, and 1502.2). For instance: (a) For projects directly undertaken by Federal agencies the environmental impact statement shall be prepared at the feasibility analysis (go no go) stage and may be supplemented at a later stage if necessary. (b) (c) (d)"

Greatly expanding the number of BSL-4 facilities in this country raises the possibilities for, and risk of unintentional releases. It is very unclear (perhaps intentionally) exactly how many new BSL-4 facilities are being planned, proposed or built. It appears that at a minimum, the number of those labs will double and will be placed across the U.S.

Rather then applying the NEPA process early, and taking a hard look at the potential for catastrophic adverse impacts stemming from the decision to fund and build many more BSL-4 facilities, NIH apparently instead chose first to build and fund the facilities and then do impact analyses on the individual labs.

The DEIS described the agents that will be studied in the proposed BSL-4 facility in Hamilton as: "Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission." (DEIS 1-5) The above statement would likely apply to each of the BSL-4 labs under consideration or construction across the nation.

The DEIS also brushed off, or otherwise dismissed out-of-hand any potentials for release of life-threatening diseases or organisms or the risks thereof. Since NIH has taken that arbitrary and capricious position (little or no risk, and no analysis) in a DEIS, it is highly likely that they will take that unreasonable "position" regarding funding and construction of BSL-4 facilities elsewhere in the country.

The anthrax released in the 2001 attacks apparently came from a United States facility. It would appear necessary to consider in an overall context, the increased potential for similar occurrences, and other potential for unintended releases, because of NIH's early **62-167** ⊀ programmatic decisions and increased funding to greatly expand those numbers of

> It appears that by their failure to apply NEPA early in the planning process, NIH has failed to comply with 40 CFR 1502.3, 1502.4, and 1502.5, et sea.

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Comment

Response

62-167

Please see Section 1.7.4 where comments regarding a programmatic

addressed.

14. RML will be prohibited by law from telling the public what BSL-4 agents are under study, and informing the public about any release of BSL-4 agents into the community.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, federal officials are specifically prohibited from disclosing information regarding what biological agents and toxins are being used in a BSL-4 lab or transported to the lab.

Federal law also prohibits the disclosure of any notification of a release, theft, or loss of a listed biological agent or toxin. Any person violating the law prohibiting public disclosure of the use of these biological agents and pathogens may be subject to a civil penalty up to \$500,000. If there is a release of biological agents and toxins from the biocontainment area, federal law gives the Secretary of Health and Human Services the sole discretion to determine if the release poses a threat to our community's public health or safety. Only upon such a determination by the Secretary, may the relevant state and local public health authorities and the public be notified. In the event of a public health emergency resulting from release from the BSL-4 lab, public health authorities and the public will not be notified until the Secretary is satisfied that such an emergency exists. If the Secretary determines the release or theft does not pose a threat, federal law ensures that the public will never know about the release or theft.

The DEIS should analyze and disclose the additional risk of delays in emergency response, inability of both the public and local responders to have the information needed to respond to a release or epidemic caused by a release of an infectious disease or agent.

The DEIS should disclose and analyze the social impacts to nearby residents of knowing that they could be at risk of exposure to an infectious disease or agent and not be told under the law.

The DEIS should disclose and analyze the affect that this law will have in creating a hesitance for new residents to live near a lab and for mobile populations to move away.

We lose local control to protect our community, our families and our children.

Comment

Response

62-168

Please see response to comment 47-6.

62-168

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Appendix A – Announcements and Reports Showing that Officials from NIH Stating the Plans to Build a BSL-4 Laboratory at RML as a Forgone Fact.

1) Q&A From NIH Website Regarding RML Expansion.

January 29, 2002: "For that research to be carried out safely for both the scientists and the community, a new 'biocontainment' facility will be constructed on the RML campus."

April 16, 2003: "For that research to be carried out safely for both the scientists and the community, NIH plans to construct an additional research facility on the RML campus."

January 29, 2002: "When will it be completed? Preliminary planning for the facility will begin immediately. The design should be finished within one year and construction may take up to two years. A stringent certification process will be required prior to its use with agents at the BSL-4 level."

April 16, 2003: "When will construction of the building be completed? Preliminary planning for the facility has been completed; the project is now in design development. An Environmental Impact Statement (EIS) is being prepared to address possible environmental impacts of the project. No construction can begin until the EIS process is completed. The design should be finished within one year; construction may take up to two years. BSL-4 laboratories also must undergo a stringent certification process before they can be used."

Ravalli Republic, "Lab to play expanded role fighting bioterrorism," February 11, 2002.

"Officials at the National Institute of Allergy and Infectious Diseases recently announced that a new research lab will be built at the Hamilton campus to help develop new diagnostics, vaccines and treatments for diseases caused by the intentional release of pathogens into human populations. In order to protect the safety of scientists and the community, [Deputy Director of the Division of Intranural Research Karyl] Barron said, a biocontainment facility will be constructed with the highest possible safety standards - known as biosafety level 4."

3) NIH Record, "New Facilities To Bolster Anti-Bioterror Effort," April 2, 2002.

"But we need some new facilities to make our program really fly," Kindt added. He said a new BSL 3/4 facility at RML has been funded, and described a new campus building dedicated to counter-bioterrorism and emerging disease research - Bldg. B,

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which will include BSL-3 labs. "Bldg. B will feature 175,000 gross square feet of space, including six floors and a ground-floor vivarium. We're in the conceptual design phase now. Groundbreaking for the new lab building is expected in mid to late 2003, with completion anticipated in 2005."

Missoulian, "Montana lab poised to lead in bioterrorism defense," April 8, 2002.

"The new lab was planned before Sept. 11 and the string of anthrax attacks that followed, administrator Pat Stewart said. Rocky Mountain already was studying organisms that could be used in biological attacks, and Stewart said existing expertise at the Rocky Mountain complex is the main reason for building the new lab there."

5) Ravalli Republic, "Leading the charge - High-level addition will propel Rocky Mountain Labs to forefront of battle on terror," April 10, 2002.

"[Dr. Thomas] Kindt told the group gathered in the Hamilton Middle School auditorium at noon that one of the finest labs of its kind will open at Rocky Mountain Laboratories this month allowing research to begin that has been backed up for years. And in another couple of years an even more secure, high-tech lab will open at the Hamilton campus."

"In order to carry out our agenda, we need a biosafety level 4 lab at Rocky Mountain Labs," he said. "We will prepare ourselves with a number of facilities."

6) Homeland Security: The Federal and Regional Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session, June 10, 2002.

http://commdocs.house.gov/committees/science/hsy80094.000/hsy80094_0.HTM

Mr. BARTLETT. "Thank you very much. I wonder if you could spend just a moment letting the audience know how unique a Level 4 containment facility is and how few of them there are in the world?"

Dr. FAUCI. "Yes. A Level 4 facility is the highest level facility for a microbe. There are very of the in this country. There is one if Fort Dietrich, there is one at the CDC in Atlanta, there is one operational in Texas and one planned in Texas. We are planning two additional ones right now, and those are the two I mentioned. The one that we are going to be partnering with the Department of Defense up at Fort Dietrich to make that a much more enhanced biodefense arena, and one that we are going to be putting in Rocky Mountain Laboratory, which is an NIH facility in Hamilton, Montana."

7) National Advisory Allergy and Infectious Diseases Council, Meeting Minutes, September 23, 2002.

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"III. ANNUAL UPDATE OF DIVISION OF INTRAMURAL RESEARCH ACTIVITIES - Thomas J. Kindt. Ph.D., Director, DIR, NIH

Dr. Kindt described facilities and staff increases in the Division of Intramural Research (DIR). The DIR staff now consists of 1,200 people, including 92 tenured scientists and 27 on tenure track. Two new facilities, Building B on campus and Twinbrook 3 in Rockville, will be constructed soon, and there will be expansions at the Rocky Mountain laboratory."

8) NIH Record, Biodefense Effort Firms Up in Post-Attack Year, October 1, 2002.

"Fauci touched briefly on a raft of research highlights: NIH, the CDC and the Department of Defense are working on a better anthrax vaccine, one that will employ a recombinant protective antigen; following "very impressive" animal trials, a phase I trial in humans of a new Ebola virus vaccine is expected in coming months, largely a tribute to the "spectacular job" done by Dr. Gary Nabel at NIH's Vaccine Research Center (a combination vaccine is also planned to combat not just Ebola but also Lassa and Marburg viruses, which also cause viral hemorrhagic fever); four new Biosafety Level 3 or higher laboratories are in the works (a BSL-3/4 lab and animal facility at Rocky Mountain Laboratories, a BSL-3/4 clinical facility at Ft. Detrick, a BSL-3 lab and vivarium in NIH's new Bldg. B and a BSL-3 lab at the Twinbrook facility in Rockville)."

9) Missoulian, "Hot Zone," September 15, 2002.

"The lab submitted requests to build a BL-4 several years ago, but nothing happened until the terrorist attacks, said Pat Stewart, the lab's chief administrator."

"Karl Johnson, the virologist who built the first BL-4 in 1978 in Atlanta and gained fame as the researcher who identified Ebola, said Hamilton and the Bitterroot Valley have nothing to worry about. BL-4 labs are safe, necessary and will allow even better research to go on in Montana. Johnson is on a committee reviewing the design plans for Rocky Mountain Labs' proposed BL-4."

Appendix B – Sample of Instances Of Serious Infections Caused by Accidental Exposure In BSL-2 to 4 Laboratories in the United States.

'BACTERIAL AGI	ENTS - Part 1		
Bacillus anthracis	Bordetella pertussis	Brucella	Campylobacter

"AGENT: Bacillus anthracis

Forty (40) cases of laboratory-associated anthrax, [Emphasis Added] occurring primarily at facilities conducting anthrax research, have been reported (66, 151). No laboratory-associated cases of anthrax have been reported in the United States since the late 1950's when human anthrax vaccine was introduced.

Naturally and experimentally infected animals pose a potential risk to laboratory and animal care personnel.

LABORATORY HAZARDS: The agent may be present in blood, skin lesion exudates, cerebrospinal fluid, pleural fluid, sputum, and rarely, in urine and feces. Direct and indirect contact of the intact and broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, and rarely, exposure to infectious aerosols are the primary hazards to laboratory personnel.

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices, containment equipment and facilities are recommended for activities using clinical materials and diagnostic quantities of infectious cultures. Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for studies utilizing experimentally infected laboratory rodents. A licensed vaccine is available through the Centers for Disease Control and Prevention; however, immunization of laboratory personnel is not recommended unless frequent work with clinical specimens or diagnostic cultures is anticipated (e.g., animal disease diagnostic laboratory). Biosafety Level 3 practices, containment equipment and facilities are recommended for work involving production volumes or concentrations of cultures, and for activities which have a high potential for aerosol production. In these facilities immunization is recommended for all persons working with the agent, all persons working in the same laboratory room where the cultures are handled, and persons working with infected animals.

"AGENT: Bordetella pertussis

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Bordetella pertussis, a human respiratory pathogen of worldwide distribution, is the causative agent of whooping cough. The disease is typically a childhood illness; however, the agent has been associated, with increased frequency, in adult illness (106, 112, 130). Several outbreaks in health-care workers have been reported in the literature (106, 112). Adolescents and adults with atypical or undiagnosed disease can serve as reservoirs of infection and transmit the organism to infants and children (135). Eight cases of infection with B. pertussis in adults have been documented at a large research institution. The individuals involved did not work directly with the organism, but had access to common laboratory spaces where the organism was manipulated. One case of secondary transmission to a family member was documented (122). A similar incident occurred at a large midwestern university resulting in two documented cases of laboratory-acquired infection and one documented case of secondary transmission (146). Other laboratory-acquired infections with B. pertussis have been reported, as well as adult-to-adult transmission in the workplace (19, 35). Laboratory-acquired infections resulting from the manipulation of clinical specimens or isolates have not been reported. The attack rate of this airborne infection is influenced by intimacy and frequency of exposure of susceptible individuals. [Emphasis Added]

LABORATORY HAZARDS: The agent may be present in respiratory secretions, but is not found in blood or tissues. Since the natural mode of transmission is by the respiratory route, the greatest potential hazard is aerosol generation during the manipulation of cultures or concentrated suspensions of the organism.

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices, containment equipment, and facilities are recommended for all activities involving the use or manipulation of known or potentially infectious clinical materials or cultures. Animal Biosafety Level 2 should be used for the housing of infected animals. Primary containment devices and equipment (e.g., biological safety cabinets, centrifuge safety cups, or specially designed safety centrifuges) should be used for activities likely to generate potentially infectious aerosols. Biosafety Level 3 practices, procedures, and facilities are appropriate when engaged in large scale production operations. The current pertussis vaccine may not provide complete and permanent immunity; however, a booster dose of pertussis vaccine is not recommended for use in persons who have passed their seventh birthday (50).

"AGENT: Brucella (B. abortus, B. canis, B. melitensis, B. suis)

B. abortus, B. canis, B. melitensis, and B. suis have all caused illness in laboratory personnel (129, 151, 176). Brucellosis is the most commonly reported laboratory-associated bacterial infection (127, 143, 151). Hypersensitivity to Brucella antigens is also a hazard to laboratory personnel. Occasional cases have been attributed to exposure to experimentally and naturally infected animals or their tissues.

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RML-Integrated Research Facility FEIS

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LABORATORY HAZARDS: The agent may be present in blood, cerebrospinal fluid, semen, and occasionally urine. Most laboratory-associated cases have occurred in research facilities and have involved exposure to Brucella organisms being grown in large quantities. Cases have also occurred in a clinical laboratory setting: direct skin contact with cultures or with infectious clinical specimens from animals (e.g., blood, uterine discharges) are commonly implicated in these cases. Aerosols generated during laboratory procedures have caused large outbreaks (95). Mouth pipetting, accidental parenteral inoculations, and sprays into eyes, nose and mouth have also resulted in infection. [Emphasis Added]

RECOMMENDED PRECAUTIONS: Biosafety Level 2 practices are recommended for activities with clinical specimens of human or animal origin containing or potentially containing pathogenic Brucella spp. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment and facilities are recommended, respectively, for all manipulations of cultures of the pathogenic Brucella spp. listed in this summary, and for experimental animal studies. Vaccines are not available for use in humans.

"AGENT: Campylobacter (C. jejuni/C. coli, C. fetus subsp. fetus)

C. jejuni/C. coli gastroenteritis is rarely a cause of laboratory associated illness. *Three laboratory-acquired cases have been documented (138, 149, 155)*. [Emphasis Added] Numerous domestic and wild animals, including poultry, pets, farm animals, laboratory animals, and wild birds are known reservoirs and are a potential source of infection for laboratory and animal care personnel. Experimentally infected animals are also a potential source of infection (155).

"LABORATORY HAZARDS: Pathogenic campylobacters may occur in fecal specimens in large numbers. C. fetus subsp. fetus may also be present in blood, exudates from abscesses, tissues, and sputa. Ingestion or parenteral inoculation of C. jejuni constitute the primary laboratory hazards. *The oral ingestion of 500 organisms caused infection in one individual (163)*. [Emphasis Added] The importance of aerosol exposure is not known.

RECOMMENDED PRECAUTIONS: Biosafety level 2 practices, containment equipment and facilities are recommended for activities with cultures or potentially infectious clinical materials. Animal Biosafety Level 2 practices, containment equipment and facilities are recommended for activities with naturally or experimentally infected animals. Vaccines are not available for use in humans.

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Appendix C – Presentation by Friends of the Bitterroot and Coalition for a Safe Lab at Town Meeting and RML Citizen's Liaison Group